

### REMARKS

Applicants thank the Examiner for the allowance of Claims 24-26.

Claim 27 is cancelled to put the application in a condition for appeal. Applicants reserve the right to file a divisional application directed to the subject matter cancelled herein.

#### 35 U.S.C. § 112 (1<sup>st</sup> Par.) Rejection of Claims 18-23 and 28-30

Claims 18-23 and 28-30 were finally rejected under 35 U.S.C. § 112 (1<sup>st</sup> Par.), because, according to the Examiner, the specification does not reasonably provide enablement for all dehydrogenations.

Applicants traverse the rejection of Claims 18-23 and 28-30 and respectfully request that the Examiner reconsider the rejection of such claims. In particular, Applicants first point out that Applicants disagree with the Examiner's characterization of one skilled in the art as only having a BS degree in chemistry. In particular, the Examiner unnecessarily limited the skilled artisan to a person not having an advanced degree in chemistry. Applicants contend that one skilled in the art is a Ph.D. organic chemist having experience in the pharmaceutical industry and familiar with the dehydrogenation processes known to those skilled in the art at the time of filing of the instant application.

Notwithstanding Applicants' position that the skilled artisan would be a Ph.D. organic chemist, Applicants maintain that the artisan – as defined by the Examiner – having a BS degree in chemistry and several years of experience, would have more than an adequate knowledge base to perform the *standard* transformation, involving dehydrogenation not only with Pd/C, but with other well known dehydrogenation techniques. One of ordinary skill in the art – once informed that the compound of Formula II could in fact undergo dehydrogenation – would have the knowledge of any number of standard dehydrogenation methods, as well as have the skills and knowledge to seek further information relating to standard dehydrogenation reactions not specifically exemplified within the specification.

The literature is replete with appropriate reagents and reactions suitable for use in dehydrogenation processes of compounds and this information is available to one skilled in the art. Applicants disagree with the Examiner in that the available literature to either a BS or Ph.D. organic chemist is limited to Organic Chemistry textbooks. Instead, there are many resources available – and known to those skilled in the art – such as

those journal articles that may be located by a sci-finder search. These searches are standard procedures for either a B.S. or a Ph.D. scientist.

The Examiner also contends that a large quantity of experimentation would be necessary, since there is no list of reagents or reaction conditions that teach every possible dehydrogenation reaction associated with the piperazine and pyrazole rings in Formula II.

This Court has repeatedly explained that a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art. Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys., 804 F.2d 659, 664 (Fed. Cir. 1986); In re Howarth, 654 F.2d 103, 105 (CCPA 1981) ("An inventor need not, however, explain every detail since he is speaking to those skilled in the art." ); In re Lange, 644 F.2d 856, 863 (CCPA 1981). We thus have noted that "not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be." In re Gay, 50 CCPA 725, 309 F.2d 769, 774 (CCPA 1962). Unless there is evidence to the contrary, therefore, *the lack of certain production details does not indicate failure of enablement*. See DeGeorge v. Bernier, 768 F.2d 1318, 1323 (Fed. Cir. 1985). In the present case, Koito simply did not provide evidence at trial that the production details omitted would have made one of ordinary skill in the art unable to practice the claimed invention without undue experimentation.

Koito Mfg. Co. v. Turn-Key-Tech, LLC, 381 F.3d 1142, 1156 (Fed. Cir. 2004).

Similarly, Applicants lack of "production details," by not providing a plethora of examples of possible dehydrogenation conditions, does not indicate failure of enablement. Applicants' invention is enabled, because one of ordinary skill is able to practice the claimed invention – the scope of which is directed to a process for the production of a compound of formula I.

Applicants point out that "[a]s long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied. . . . Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. § 112. MPEP § 2164.01(b). The C.C.P.A. held in In re Marzocchi, 169 U.S.P.Q. 367 (C.C.P.A. 1971),

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with enabling requirement of the first

paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support."

Id. at 369.

Applicants submit that the specification of the instant application teaches a complete process of making and using the invention – a process for the production of compound I – by providing examples of ways to dehydrogenate the compound of formula II. This disclosure does bear a reasonable correlation to the *entire scope* of the claim – the ultimate scope of which is directed to a process for the production of compound I. The scope of the entire claim is not directed simply to "dehydrogenations."

The Examiner also contends that the catalytic reaction exemplified by Applicant's working examples are inherently understood to be unpredictable, citing, *inter alia*, Mobil Oil Corp. v. W.R. Grace & Co., 180 USPQ 418. Applicants submit that the dehydrogenation reactions exemplified in the specification are not related to those described in Mobil Oil Corp. (noting that the *gas oil cracking catalyst art* had made no significant improvement in petroleum catalytic cracking during 20 years of well-organized, active, and expensive research effort in this sensitive catalytic field of chemical magic and unpredictable results). Applicants invention is directed to the production of a compound of Formula I that incorporates in one of the production details, a dehydrogenation step.

Even if dehydrogenation reactions are unpredictable and would require some experimentation,

"[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). " 'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.' " *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this consideration and are not the controlling factors. *United States v. Teletronics Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). . . . Time and difficulty of experiments are not determinative if they are merely routine. Quantity of examples is only one factor that must be considered before reaching the final conclusion that undue experimentation would be required. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

MPEP § 2164.05(b).

Applicants submit, as stated earlier, that ample guidance is provided for the dehydrogenation production step, which is routine for those skilled in the art. The amount of time and difficulty of dehydrogenating the compound of formula II is not a determinative factor. Instead, the focus should be the enablement of the scope of the entire claim, of which, Applicants have supplied sufficient disclosure.

Finally, § 2164.04 of the MPEP specifically states that the Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention.

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. . . . As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). . . . The language should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact.

Applicant submits that the Examiner did not establish a prima facie case and is without factual evidence to support or explain why the truth or accuracy of Applicants' statements are doubted. Instead, the rejection is based on conclusory statements about the amount of experimentation, based upon undergraduate Organic Chemistry textbooks, without any supporting evidence (e.g. publications) from sources on which one skilled in the art would rely. The Examiner does not provide evidence that other dehydrogenations not exemplified by Applicant will not work on the pyrimidone at issue. Therefore, the statements in the present application must be taken as the truth. In re Marzocchi, 169 U.S.P.Q. 367 (C.C.P.A. 1971).

Applicants submit that Claims 18-23 and 28-30 are enabled, such that one of ordinary skill in the art could perform the dehydrogenation reaction required therein. Accordingly, Applicants respectfully request that the Examiner reconsider the rejection of Claims 18-23 and 28-30.

#### CONCLUSION

Having addressed all points and concerns raised by the Examiner, Applicants respectfully request an early and favorable action in this application.

Respectfully submitted,

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